UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,919	09/12/2003	William J. Taylor	P0008059.00	8345

27581 7590 11/09/2009

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,919	TAYLOR ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14,16,18-24,26-36,38,40-48,50-57,59,61-65 and 68-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,16,18-24,26-36,38,40-48,50-57,59,61-65 and 68-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 5, 7-14, 16-22, 25-36, 38-45, 48- 57, and 59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifried et al. (US 5,531,003) in view of Stevenson (US 6,008,980) and in view of Dahlberg et al. (US 5,245,999).

4. Seifried discloses a feedthrough assembly comprising a ferrule (10) having an inner surface and an outer surface, a terminal (electrical pin lead 12) extending through said ferrule, a conductive noble metal coating of gold, platinum, or palladium (Col. 3, lines 1-49), an insulating body formed through an insulating seal (Col. 2, line 15-20). Seifried discloses that the feedthrough assembly is to be used with an implantable pulse

generator, which includes an encasement or container having electrical components disposed within the container (Col. 2, lines 1-35). Seifried discloses the ferrule to run into the container of the IPG to make electrical connection to the components disposed within (Col. 2, lines 24-34).

5. Seifried fails to disclose a second conductive coating of a noble metal. Stevenson et al. teaches that it is known to use a process for sputtering down an adhesion layer of titanium, and electroplating nickel over it, and finally gold is sputtered over the nickel layer in feedthrough systems, specifically at one end of the terminal adjacent to the brazes, as set forth in Col. 7, line 1-14 for providing the predictable results of the first conductive coating serves as an adhesive, to displace surface oxide and provide for greater conductive contact and increased depositing of the second coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Seifried with a second metallic coating of a noble metal, where the first coating serves as an adhesive as taught by Stevenson, since such a modification would provide the predictable results of a second metallic coating of a noble metal, where the first metal serving as an adhesive provides for displacement of surface oxidation and providing for greater conductive contact and increased depositing of the second coating.

6. Seifried et al. and Stevenson et al. fail to specifically disclose a second connector for electrically coupling and mechanically engaging the ferrule outer surface with a second electrical contact coupled to the electrical device. It is well known in the art to utilize a second connector for electrically coupling and mechanically engaging the

ferrule outer surface with the pacemaker circuitry in order to enable the pacemaker to operate in an unipolar mode (that is, the housing, which is attached to the ferrule, of the pacemaker is utilized as the ground electrode in electrical stimulation of the heart). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Seifried in view of Stevenson with a second connector for electrically coupling and mechanically engaging the ferrule outer surface with a second electrical contact coupled to the electrical device, since such a modification would provide the system with the predictable results of enabling the pacemaker to operate in an unipolar mode (that is, the housing, which is attached to the ferrule, of the pacemaker is utilized as the ground electrode in electrical stimulation of the heart).

7. Dahlberg et al. teaches a feedthrough apparatus for a pacemaker that permits unipolar operation of the pacemaker. The feedthrough (1)includes a case 3 (i.e., a ferrule) which extends through the pacemaker housing (2), wherein the case encloses an insulating compound (4) through which a conductor or terminal pin (5) runs (see, for example, col. 4, lines 20-32). In order to enable a unipolar connection, connecting means 9 electrically and mechanically connects the outer surface of case 3 to an indifferent pole 10 of the stimulating pulse generating circuitry 26 of the pacemaker (see, for example, col. 4, lines 33-66). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the feedthrough assembly of Seifried et al in view of Stevenson et al. such that a second connector electrically and mechanically connects the ferrule outer surface to the circuitry of the

pacemaker as taught by Dahlberg et al. since such a modification would provide the predictable results of enabling the pacemaker to function in a unipolar stimulation mode, thereby requiring only one stimulation electrode for pacing the heart.

8. With respect to claims 2 and 45, Seifried et al. discloses that the conductive metal coating (30) also covers an area of said terminal adjacent to said body of insulation material (see Fig. 1).

9. With respect to claims 5, 35, and 48, Seifried et al. discloses that the conductive metal coating entirely covers said terminal (see Fig. 1).

10. With respect to claims 9-11, 25, 28-30, and 52-54, Seifried et al. discloses that the conductive metal coating is a noble metal or a noble metal alloy (see col. 3, lines 35-40). Seifried et al. discloses that the conductive metal coating may be gold, platinum, palladium, and titanium (see col. 3, lines 35-40).

11. With respect to claims 7-8, 26-27, and 50-51, Seifried et al. discloses a feedthrough assembly comprising a conductive metal coating covering the terminal said coating being more resistant to oxidation than said terminal (a metallic film or coating 30 is placed on the pin to minimize and control the growth of the oxide thereon; see col. 3, lines 1-25). Seifried discloses that the conductive metal coating may be gold, platinum, palladium, and titanium (see col. 3, lines 35-40), but fails to specifically disclose that the conductive metal coating may be rhodium or ruthenium. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to substitute either rhodium or ruthenium as the conductive metal coating since such a modification would

provide the predictable results of minimizing and controlling the growth of oxidation on the terminal would be within the level or ordinary skill in the art.

12. With respect to claims 12-13, 31-32, and 55-56, Seifried et al. discloses that the thickness of the coating is not critical so long as it is substantially continuous in its coverage. It may range from 500A to about 10,000A (see col. 3, lines 20-25).

13. With respect to claims 14, 36, 57, and 65 Seifried et al. discloses that the terminal (pin 12) is a refractory metal or a refractory metal alloy (tantalum or niobium).

16. With respect to claims 4, 16, 38, 59, and 65, Dahlberg et al. fails to disclose that the connector is a spring contact. As admitted by Applicant at page 9, spring devices are well known in the art for ensuring an electrical connection between two structures. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to utilize a spring device as the connector because the selection of any connector in would be within the level or ordinary skill in the art for providing the predictable results of ensuring an electrical connection between the two structures

14. With respect to claims 17, 39, and 60, Stevenson et al. discloses that the second conductive coating is a noble metal (gold).

15. With respect to claims 18-19, 40-41, and 62-63, Stevenson et al. discloses that since the ferrule is often formed of a material susceptible to oxidation, such a coating helps guarantee a long term electrical connection which will remain oxide free, but fails to specifically disclose that the conductive coating may be titanium or niobium. It would have been obvious to one having ordinary skill in the art at the time of applicant's

invention to substitute either titanium or niobium as the conductive coating because the selection of any conductive metal would be within the level or ordinary skill in the art for providing the predictable results of establishing a reliable electrical connection which is also resistant to oxidation

16. With respect to claims 20-21, 42-43, and 63-64, Stevenson et al. fails to disclose the specific thickness of the conductive pad attached to the ferrule. However, Seifried et al. discloses that a satisfactory thickness of a conductive coating that is resistant to oxidation may range from 500A to about 10,000A (see col. 3, lines 20-25).

17. With respect to claim 22, Seifried et al. discloses that the feedthrough assembly of Seifried used in an IPG is necessarily manufactured according to the method of claim 22.

18. With respect to claims 33 and 34, Seifried et al. discloses that the protective metal coating may be applied over the entire pin or it may be applied to only specific portions of the pin (see col. 3, lines 15-20). Seifried et al. fails to specifically disclose that forming the conductive coating includes mechanically or chemically masking areas that are not to be coated with the conductive material (i.e., areas adjacent to the pin or areas on the pin). Masking is a well-known methodology for applying selective coatings (see Stevenson et al. which uses paper mask 44 to shield areas on the feedthrough apparatus which are not to be coated). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to mechanically or chemically mask areas that are not to be coated with the conductive material for providing the

predictable results of effectively applying the conductive coating only on the desired area (i.e., avoid coating areas adjacent to the pin or areas on the pin that are not desired to be coated).

19. Claims 3, 23, 46, 68, 70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifried et al. (US 5,531,003) in view of Stevenson et al. (US 6,159,560) and in view of Dahlberg (US 5,245,999) as applied above and further in view of Pless et al. (US 5,131,388).

20. Seifried in view of Stevenson and in view of Dahlberg disclose the invention as claimed as applied above, but fail to teach the connection of the feedthrough pin by a mechanical means such as by crimping. Pless teaches that it is known in the medical implant art to crimp the internal electronics of an implantable medical device to provide connection to the feedthrough apparatus as set forth in Col. 4, line 36, for providing an alternative to welding, which is known to be a less complicated connection means as well as less expensive. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Seifried in view of Stevenson and in view of Dahlberg, with crimping to provide a connection to the feedthrough apparatus of the internal hybrid electronics since such a modification would provide the predictable results of a system with a less expensive and complicated manner of production.

21. Claims 4, 16, 24, 47, 65, 68, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifried et al. (US 5,531,003) in view of Stevenson et al. (US 6,159,560) and in view of Dahlberg (US 5,245,999) as applied above and further in view of Langer (4,254,775).

22. Seifried in view of Stevenson and in view of Dahlberg disclose the invention as claimed as applied above, but fail to teach the connection of the feedthrough pin by a mechanical means such as by using a spring element.

23. Langer teaches that it is known in the medical implant art that a leaf spring may be used to provide connection of internal hybrid electronics, by forcing hybrid electronics to contact through some spring force, to the feedthrough apparatus pin as set forth in Col. 5, line 44-59, for providing the predictable result of ensuring contact between the internal electronics and the pins. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Seifried in view of Stevenson and in view of Dahlberg, with providing connection of the feedthrough pin by a mechanical means such as by using a spring element, since such a modification would provide the system with the predictable result of ensuring contact between the internal electronics and the pins. It is also of not that the claims may be interpreted as reading on any spring connection of the feedthrough apparatus, and not necessarily a spring connection between the internal hybrid electronics and the feedthrough assembly as the claim states that only a connection between the feedthrough assembly and the implantable medical device is created.

24. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Seifried in view of Stevenson and in view of Dahlberg and further in view of Langer with placing the spring contact in direct connection with the ferrule since such a modification would provide the predictable results of providing direct contact to the feedthrough pin, which would require a spring with a smaller spring constant which would inherently reduce the size of the spring, thereby reducing the overall size of the implant. Moreover, it has been held that rearranging of parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70.

Response to Arguments

25. Applicant's arguments with respect to claims 1-5, 7-14, 16, 18-24, 26-36, 38, 40-48, 50-57, 59, 61-65, 68-72 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762
/Joseph Stoklosa/
Examiner, Art Unit 3762
11/5/2009